

EXHIBIT L

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ETHICON

cc: Mr. E. Block

to

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Dr. R. Kronenthal

to

Dr. A. J. Levy

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Dr. J. McDivitt

RDCF

To: Dr. A. J. Melveger**Subject:** CRACK DEPTH IN EXPLANTED
PROLENE* POLYPROPYLENE SUTURES

A study was carried out of all available SEM photographs of explanted PROLENE sutures, to determine best estimates for the penetration depth of surface cracks. The micrographs were taken in 1981; the explants themselves are no longer available. SEM photographs examined were as follows:

Photo #	Date	Source of PROLENE Explants
5853-5874	7/27/81	ERF #81-266, sizes 4-0 and 5-0, cardio-vascular implants, 5 and 7½ years implantation time.
5627-5641	3/2/81	R. C. Drews, M.D. Size 10-0.
5767-5789	6/18/81	Ophthalmic implants, 2 months through 4½ years implantation time.

The 10-0 sutures showed surface cracks after 1-2 years implantation; the larger sutures after 7½ years but not at 5 (although cracks could be induced by abrasion on the 5 year explant, as previously reported by Dr. Borysko). Of those micrographs exhibiting surface cracks, three showed a clear, edge-on view of the cracked surface layer, permitting an accurate measurement of crack depth. Seven micrographs showed oblique views of cracks, from which only an estimate ($\pm 50\%$) of depth could be obtained. The data from all ten micrographs are shown in Table I.

The 10-0 sutures have crack depths of 0.5 to 2 μm ; the suture diameter is 25 μm . Crack depth does not vary systematically with implantation time; it does vary significantly from point to point along the fiber length in both the 10-0 and the 4-0 sutures.



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Attachment

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TABLE I
Crack Depth in PROLENE Explants

Explant Specimen	Suture Size	In vivo Time Yr	SEM Photo #	Magnif.	Crack depth μm
ERF #81-266 (cardiovascular)	4-0	7½	5872	2000 X	4.5*
			5873	2000 X	4 *
			5874 A/B	2000 X	2-4*
From Dr. R. C. Drews:					
A. Belikopitsky	10-0	2	5769	1000 X	1-1.5 ⁺
E. Lucksinger	10-0	3	5783	~1700 X	1 ⁺
A. Karchmer	10-0	3½	5780	1000 X	1.5 ⁺
			5781	1000 X	2 ⁺
Baum	10-0	4½	5633	2000 X	0.5-0.8 ⁺
			5637	2000 X	0.5-0.8 ⁺
			5641	1000 X	2 ⁺

* Edge-on view of cracks

+ Oblique view of cracks